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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,215	TOYODA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Jan. 21, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-15,17 and 19-25* is/are pending in the application.

4a) Of the above claim(s) *6,7,13 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-11, 14, 15, and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Jan. 21, 2009 are acknowledged and have been fully considered. Claims 12, 16, and 18 are cancelled; claims 9-11, 13-15, and 17 are amended; claims 6, 7, 13, and 17 are withdrawn; claims 19-25 have been added.

The objection to the abstract is maintained, since no action has been taken to address the issue raised by the examiner in the prior Office action.

The objection to the specification is maintained, since no action has been taken to address the numerous instances of improper grammar and/or non-idiomatic English present throughout the specification that were noted in the prior Office action.

The objections to claims 1-5, 8-11, and 14 are withdrawn in light of the claim amendments.

The objection to claim 15 is maintained since the incorrect article has been inserted at the beginning of the claim (see the 1st paragraph under Claim Objections in the prior Office action).

The objections to claims 12, 16, and 18 are moot in light of the claim cancellations.

The rejection of claims 12 and 16 under 35 U.S.C. 112, 2nd paragraph is moot, in light of their cancellations.

The rejection of claims 1-4, 8-10, 14, and 15 under 35 U.S.C. 102(b) over CHEN is maintained as discussed below.

The rejection of claims 1 and 11 under 35 U.S.C. 102(b) over COMPTON is maintained as discussed below.

The rejection of claims 1 and 5 under 35 U.S.C. 103(a) over CHEN in view of SHIMIZU is maintained as discussed below.

The rejection of claims 12 and 16 under 35 U.S.C. 103(a) is moot in light of the claim cancellations.

The rejection of claim 18 under 35 U.S.C. 103(a) over CHEN in view of SRIWONGJANYA is moot in light of the claim cancellation.

New grounds of rejections for claims 19-25 are set forth below.

Abstract (Maintained)

The abstract is objected to since it fails to appropriately describe the disclosed invention. In particular, an "argininic acid" salt is not disclosed in the specification and does not appear to be a component of the invention in any embodiment. Thus, the current abstract is inaccurate.

Specification (Maintained)

The specification is objected to since numerous instances of improper grammar and/or non-idiomatic English have been noted throughout the disclosure. It is requested

that applicant review the specification and correct the language where appropriate to provide a clearer and more easily understandable disclosure. In addition to various grammatical mistakes, non-standard terms have been used, for instance the phrase "thrown into water" (paragraphs [0007], [0009], [0013]-[0015], [0048], and [0049]) is not commonly used and is awkward.

Claim Objections (Maintained)

Claim 15 is objected to because of the following informalities: this independent claim should begin with the article "A". Furthermore, as pointed out in the prior Office action, the phrase "throwing the dry syrup preparation of claim 1 into water" is not commonly used and is awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (1st Paragraph)

Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed Jan. 27, 2006 has introduced NEW MATTER into the claims. New claims 19 recite a dry syrup preparation *consisting essentially of* loratadine, at least one binder, and a sugar. Written description support is lacking for the language "consisting essentially of", as is instantly claimed. Specifically, this phrase is not

present in the original disclosure. In the absence of support for dry syrup preparations "consisting essentially of" the recited components, the recitation "consisting essentially of" in claims 19-25 is new matter and must be removed from the claims.

The response did not point out where support for new claims 19-25 could be found in the originally filed disclosure, other than broadly asserting that such support "can be found in the specification". The examiner has been unable to locate proper support for "consisting essentially of" in the specification. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claims 19-25 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in amended claims 19-25, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 19-25 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Claim Rejections - 35 USC § 102 (Maintained)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-10, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by CHEN (U.S. 2003/0077297; Published Apr. 24, 2003).

1. It is noted that "dry syrup preparations" are defined as "preparations which are dissolved or suspended before use" in the instant specification (paragraph [0003]). This definition is extremely broad and does not limit the physical properties of the claimed dry syrup preparations. Thus, the dry syrup preparations, as defined herein, can be any preparation able to be dissolved or suspended prior to use.

2. Chen discloses formulations in which active agents are suspended in a carrier vehicle (abstract; paragraph [0012]). In these formulations, a first portion of the active agent is in the form of solid particles which are suspended in the vehicle and a second portion of the active agent is solubilized (i.e. dissolved) in the vehicle (paragraph [0012]). Thus, the active agents of Chen are dissolved or suspended before use and represent dry syrup preparations as defined in the instant specification. Chen teaches the use of antihistamines including loratadine as preferred hydrophobic active agents in their formulations (paragraphs [0058], [0071], [0093], and [0108]; claims 47, 114). Chen also teaches the use of binders and stabilizing agents such as hydroxypropyl cellulose (paragraph [0275]). These formulations are highly water-dispersible (paragraph [0018]) and therefore provide uniform dispersion when added to water. Chen also teaches the use of sucrose (i.e. a sugar, or saccharide) (paragraphs [0172] and [0223]). Thus, Chen reads on instant claims 1-4, 8-10, 14, and 15.

3. It is noted that claim 15 is a product-by-process type claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The MPEP states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113.

4. Claim 15 is drawn to a dispersion provided by "throwing the dry syrup preparation of claim 1 into water and stirring". The substance and structure of the claimed dispersion is not affected by this limitation, which merely reflects one version of a process that could be used to make the product. If the product in this claim is the same as or obvious from a *product* of the prior art, the claim is unpatentable. The dispersion is clearly disclosed in the prior art (see the discussion above), thus claim 15 is rejected as unpatentable over Chen.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the definition of a dry syrup has been misconstrued by the Office, and therefore Chen does not disclose a dry syrup (page 5 of the response). Applicants argue that Chen does not disclose the problem cited in the instant application and that Chen does not disclose specific examples with loratadine (page 6 of the response).

Applicants point to "paragraph 10" (page 1) of the specification (i.e. paragraph

[0003]) of the pre-grant publication as allegedly supporting a definition of the term "dry syrup" that is materially different than the one used in the prior Office action. The relevant paragraph states:

> There are various types of pharmaceutical preparations such as tablet, powder, granule, capsules etc. Among them, a dry syrup preparation means "preparations which are dissolved or suspended before use" according to general rules for preparations in the Japanese pharmacopoeia. This is the preparation especially for patients like children who dislike a medicine or elderly persons having difficulty swallowing, and even the children and/or the elderly persons can easily take it. Furthermore, the preparation is handy, and weighing and preparing divided powder of this preparation are easy.

Applicants state that all of the 3rd and 4th sentences (underlined on page 5 of the response) should be included in the definition, and further suggest that by including these sentences, one must somehow arrive at the conclusion that a dry syrup preparation is available to the consumer as a powder. The examiner cannot agree. The 3rd and 4th sentences of the above paragraph are clearly not part of the formal definition of the term "dry syrup" provided in the 2nd sentence of the paragraph. Rather, the 2nd sentence states, "...a dry syrup preparation means “preparations which are dissolved or suspended before use”..." This is the definition provided by applicant, and the examiner properly utilized this definition to apply prior art that is fully consistent with this definition. The remainder of the above paragraph in no way represents a proper definition of the term "dry syrup", and at best represents intended uses of such compositions. Moreover, there is nothing in the above paragraph that indicates that the "dry syrup" preparation must be available to consumers as a powder. In paragraph 1 of the prior Office action, the examiner noted that the definition provided by applicants is extremely broad.

Since Chen does, in fact, disclose a preparation that is a "dry syrup" as defined

in the instant specification, the rejections over Chen are proper and are maintained.

In response to applicant's argument that Chen does not recognize the problem addressed by the instant application, applicant is reminded that "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

Furthermore, in regards to anticipation, the MPEP 2131.02 states:

> A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication."). *Id.* at 1718. See also *In re Sivaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982) (The claims were directed to polycarbonate containing cadmium laurate as an additive. The court upheld the Board's finding that a reference specifically naming cadmium laurate as an additive amongst a list of many suitable salts in polycarbonate resin anticipated the claims. The applicant had argued that cadmium laurate was only disclosed as representative of the salts and was expected to have the same properties as the other salts listed while, as shown in the application, cadmium laurate had unexpected properties. The court

held that it did not matter that the salt was not disclosed as being preferred, the reference still anticipated the claims and because the claim was anticipated, the unexpected properties were immaterial.).

In the instant case, the prior art clearly discloses antihistamines, specifically loratadine as useful in the invention. Furthermore, loratadine is taught as a *preferred* hydrophobic active agent in paragraph [0093]. Of the compounds listed in paragraph [0093], only 6 (including loratadine) are antihistamines (compare paragraphs [0071] and [0093]). Thus, one in possession of Chen seeking to produce an antihistamine composition would be led to those 6 preferred antihistamines and would easily and immediately have envisioned using loratadine in the composition.

Applicants argue that "Chen allegedly discloses the use of liquid binders, which is not the same as the binders used in the present invention." This argument is confusing as it was not stated that Chen discloses liquid binders (applicants have not pointed out where this statement was allegedly made). Furthermore, the claims only recite that a binder is used, and do not limit the binder to a particular type thereof (e.g. solid or liquid). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the type of binder) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

More importantly, Chen discloses the very same binders as claimed, namely hydroxypropyl cellulose (among others recited in instant claim 3) (paragraph [0275]). The physical properties of a chemical are inherent to its structure, so the hydroxypropyl

cellulose taught by Chen must have the same properties as that instantly claimed, absent evidence to the contrary. Thus, the point intended by the above argument is not apparent and the argument is not persuasive.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by COMPTON (U.S. 2003/0059471; Published Mar. 27, 2003).

5. Compton discloses flakes containing drugs (abstract; paragraphs [0012] and [0013]). These flakes are intended to be used as part of various administration forms, including suspensions as in syrups and elixirs (paragraph [0315]). In this case, the flakes are suspended in aqueous solutions before use and represent dry syrup preparations as defined in the instant specification. Compton teaches the use of antihistaminic agents including loratadine in their formulations (paragraphs [0147], line 13 and [0292], page 24, column 2, middle of the page). Compton also teaches the use of normal pharmaceutical excipients such as binders (paragraphs [0032] and [0304]) and teaches the use of hydroxypropyl cellulose (paragraphs [0055] and [0056]). The compositions taught by Compton are prepared by uniformly associating the compounds with a liquid carrier (i.e. water), thus providing a uniform dispersion upon mixing with the liquid carrier (paragraph [0314]). Compton also teaches the use of sugars including sucrose (paragraph [0058]). Compton does not disclose the use of surfactants or defoaming agents. Thus, Compton reads on instant claims 1 and 11.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive.

Applicants argue that the rejection of claims 1 and 11 over Compton requires picking and choosing, and therefore Compton does not anticipate the claims (page 6 of the response).

It is noted that applicants have not pointed out precisely what elements are required to be selected from Compton, and therefore, have not adequately defined how the reference fails to anticipate the claims. The examiner notes that Compton was only used in the rejection of claims 1 and 11, whereas applicants' arguments seem to suggest that *all* of the instant claim limitations must be met by Compton, which is incorrect. Rather claim 1 requires only loratadine, *any* binder, and *any* sugar. Claim 11 is further limiting only in the fact that it excludes surfactants or defoaming agents. As pointed out in paragraph 6 of the prior Office action, Compton does not teach surfactants or defoaming agents. Thus, to meet claims 1 and 11, Compton must only allow one to readily envisage a composition comprising loratadine, *any* binder, and *any* sugar, which Compton does. It is acknowledged that Compton discloses many species of binders and sugars. However, selecting loratadine with *any* one of these (or any combinations thereof) reads on the claims. When virtually any combination of selected ingredients would read on the claim, picking and choosing becomes irrelevant since almost any combination selected would read on the claim. The only *specific* ingredient that must be selected is loratadine. The arguments presented *supra* for the selection of loratadine from the Chen reference are applicable to Compton as well. The list of antihistamines taught by Compton is not so extensive so as to preclude the skilled artisan from immediately envisioning the use of loratadine in the compositions. Thus,

claims 1 and 11 are anticipated.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of SHIMIZU (U.S. 5,824,339; Issued Oct. 20, 1998).

6. Chen teaches the dry syrup preparation of instant claims 1-4 as discussed above. Chen is silent as to the specific type of hydroxypropyl cellulose used.

7. Shimizu discloses compositions comprising solid forms of active substances which are useful in preparing uniform suspensions (abstract; column 3, lines 18-21). Since the active agent in these compositions is uniformly suspended, the active agents of Shimizu are suspended before use and represent dry syrup preparations as defined in the instant specification. Shimizu teaches the use of additives such as binders (column 6, line 40) and teach the use of water-soluble polymers including hydroxypropyl cellulose (HPC) (abstract; column 4, line 40). In particular, Shimizu teaches the use of HPC of the SSL type (HPC-SSL) which has a different level of hydroxypropoxy substitution and different viscosity modifying properties than lower-substituted HPC (column 4, lines 55-65; examples 1 and 3). This is the same type of hydroxypropyl cellulose utilized in the instant application (instant paragraph [0040]), and necessarily has the same properties (i.e. the viscosity of a 2% aqueous solution is below 3.0 mPa•s at 20 °C). Since both Chen and Shimizu are concerned with the production of improved pharmaceutical suspensions, and since Chen teaches hydroxypropyl cellulose, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute one known component (i.e. HPC-SSL) for another (HPC) in the compositions of Chen. One would have been motivated to do so to produce a

suspension having the desired viscosity and organoleptic properties, reading on instant claim 5.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants argue that Shimizu requires elements not present in the instant claims (page 7 of the response).

Applicants' argument is not persuasive because the open language recited in the claims (i.e. comprising) does not exclude other elements from being present in the composition. Additionally, it is noted that Chen teaches all the elements of instant claims 1 and 5 including the hydroxypropyl cellulose binder. Chen does not teach the specific type of hydroxypropyl cellulose used. Thus, the teachings of Shimizu are relied upon only for the teaching and motivation for the use of the specific type of hydroxypropyl cellulose, as discussed *supra*.

The combination of Chen and Shimizu is proper, and the rejection is maintained.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by CHEN (U.S. 2003/0077297; Published Apr. 24, 2003).

8. It is noted that "dry syrup preparations" are defined as "preparations which are dissolved or suspended before use" in the instant specification (paragraph [0003]). Claims 19-25 are drawn to a medicine comprising a dry syrup preparation, wherein the dry syrup preparation consists essentially of loratadine, at least one binder, and a sugar. There are several issues with this claim language. First, as noted above, the language "consisting essentially of" is new matter. Second, given that the medicine comprises the dry syrup preparation, the language "consisting essentially of" is rendered moot since the medicine composition can comprise other components. Third, even if, *in arguendo*, the comprising language were eliminated from the claim, the "consisting essentially of" language would still not be properly defined.

9. Regarding claims 19-25, the MPEP states that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed

invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Furthermore, the MPEP states that if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

10. In the instant case, there is no discussion of the phrase "consisting essentially of" in the specification at all. In fact the phrase does not appear in the specification. Further, there is no clear indication in the specification or the claims of what the basic and novel characteristics of the invention actually are. Thus, the phrase "consisting essentially of" would be construed as equivalent to "comprising."

11. Thus, claims 19-22 and 24 are rejected for the reasons of record as applied to claims 1-4, 8-10, 14, and 15 above.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of SHIMIZU (U.S. 5,824,339; Issued Oct. 20, 1998).

12. The same arguments regarding the claim language for claims 19-22 and 24 (see the discussion *supra*) are also applicable to the claim language of claim 23. Thus, claim 23 is rejected for the reasons of record as applied to claims 1 and 5 above.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of SRIWONGJANYA (U.S. 2003/0049319; Published Mar. 13, 2003) and CARCELLER (U.S. 5,407,941; Issued Apr. 18, 1995).

13. Chen teaches the dry syrup preparation of instant claims 1-4 as discussed above. While Chen teaches the use of loratadine, hydroxypropyl cellulose, sucrose, and colloidal silicon dioxide (i.e. silicon dioxide hydrate) (paragraph [0275]) in their formulations, they do not teach the use of these components in the claimed % weight ranges of instant claim 25.

14. Sriwongjanya discloses pharmaceutical formulations for the administration of antihistamines including loratadine (abstract; Figure 3; paragraphs [0043] and [0051]). Sriwongjanya teaches the use of from 0.1-5% antihistamine (i.e. loratadine), 0.5-10% of a binder, which may be hydroxypropyl cellulose (paragraph [0030]), 0.1-5% of a lubricant, which may be silicon dioxide (paragraph [0032]), with the remaining weight of the formulation consisting of a matrix core that may include sucrose (paragraph [0031]; see paragraph [0037] and the table therein). Sriwongjanya does not teach sucrose in the weight % range of 90.0-98.75%.

15. Carceller disclose pharmaceutical compositions containing antihistamines that are loratadine analogues (abstract; structures in column 2, especially compound 4). These compositions may take a number of forms including syrups (column 13 table,

lines 15-20). In this embodiment sucrose is present in 98.4% by weight (using the dry components of the syrup per the definition of a dry syrup in the instant application) and the loratadine analogue (compound 4) is present at approximately 0.9%.

16. Since Chen, Sriwongjanya, and Carceller are each concerned with the production of pharmaceutical formulations containing antihistamines (loratadine and its analogues), it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate each of these known components into the dry syrup formulations of Chen based on the percent weight ranges taught in the art to achieve a formulation with the desired organoleptic and physical properties, reading on instant claim 25.

17. The same arguments regarding the claim language for claims 19-22 and 24 (see the discussion *supra*) are also applicable to the claim language of claim 25. Thus, claim 25 is rejected as obvious over Chen, Sriwongjanya, and Carceller.

Summary/Conclusion

Claim 15 is objected to; claims 1-5, 8-11, 14, 15, and 19-25 are rejected; claims 12, 16, and 18 are cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643